

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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| <b>AMGEN INC.,</b>                                    | : |   |
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| <i>Plaintiff,</i>                                     | : |   |
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| <b>v.</b>   | : | <b>Civ. No. 16-853-MSG<br/>CONSOLIDATED</b> |
|   | : |   |
| <b>AMNEAL PHARMACEUTICALS<br/>LLC, <u>et al.</u>,</b> | : |   |
|   | : |   |
| <i>Defendants.</i>                                    | : |   |
|   | : |   |

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**MEMORANDUM OPINION**

**GOLDBERG, J.**

**September 18, 2019**

The current dispute between the parties revolves around a settlement agreement in a Hatch-Waxman patent infringement case.

Plaintiff Amgen, Inc. (“Amgen”) originally brought claims against Defendants Sun Pharmaceutical Industries, Ltd., Sun Pharma Global Fze, and Sun Pharmaceutical Industries, Inc. (collectively, “Sun”) in response to Sun filing an Abbreviated New Drug Application (“ANDA”) for its generic Cinacalcet tablets. The Parties settled, entered into a Litigation Settlement Agreement (“Agreement”) on October 24, 2017, and thereafter stipulated to dismissal of all claims against Sun. As detailed more fully below, part of this Agreement set forth Amgen’s obligations if other manufacturers of generic Cinacalcet entered the market at risk.

From December 28, 2019 to January 2, 2019, generic manufacturer Watson Laboratories, Inc. (“Watson”) and its corporate parent Teva Pharmaceutical Industries Ltd. (“Teva”) released a generic Cinacalcet into the market. In response to Teva’s launch, Sun filed the present motion to enforce the Agreement. Sun asserts that, based on Teva’s market activity and Amgen’s deficient response, the Agreement grants a license to Sun and allows it to launch and sell its generic

Cinacalcet product.<sup>1</sup> (Oral Ar. Tr. at 21, ECF No. 481, June 13, 2019). For the reasons set forth below, I conclude that Sun has misconstrued its rights under the Agreement, and that the Agreement does not entitle Sun to a license to sell and market its generic Cinacalcet product.

## I. BACKGROUND

### A. The '405 Patent

The '405 patent, entitled “Rapid Dissolution Formulation of Calcium Receptor-Active Compound,” was issued on June 28, 2016 and assigned to Amgen. Amgen also holds an approved New Drug Application (“NDA”) No. 21-688 for Cinacalcet hydrochloride tablets. (Id.) Amgen sells Cinacalcet hydrochloride tablets in the United States under the tradename Sensipar®. (Id.)

On September 29, 2016 Amgen sued Sun, alleging that Sun infringed the '405 patent. (Compl., ECF No. 1 in C.A. No. 16-cv-882, at ¶ 7.)<sup>2</sup> The original complaint asserted that Sun committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA to obtain approval to engage in the manufacture, use, sale, or importation of its generic Cinacalcet hydrochloride before the expiration of the '405 patent. (Id. at ¶ 40.) On February 23, 2017, Amgen’s suit against Sun was consolidated with other cases brought against several other drug manufacturers that filed similar ANDAs for generic Cinacalcet products.

On October 24, 2017, Sun and Amgen settled this infringement action by entering into the Agreement at issue. (Agreement, ECF No. 437-1.) The parties do not dispute that the Agreement is binding, enforceable, and governs the present dispute. Under the Agreement, Sun filed a

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<sup>1</sup> Sun also requests limited discovery concerning the Amgen-Teva agreement, followed by an evidentiary hearing. Because I disagree with Sun’s reading of the Agreement, I will not order discovery as requested.

<sup>2</sup> All citations are to the docket for C.A. No. 16-853 unless noted otherwise.

stipulation of dismissal conceding that the '405 patent was valid and enforceable, and would be infringed by "the manufacture, use, sale, offer to sell, importation or distribution [of its generic Cinacalcet product] in or for the United States ...." (Stip. of Dismissal, ECF No. 248, at ¶ 4.) The Honorable Gregory M. Sleet (now retired), who was originally assigned to this case, signed the aforementioned stipulation of dismissal on November 2, 2017, terminating the civil case against Sun. (Dismissal Order, ECF No. 253.)<sup>3</sup>

### **B. The Teva Launch and Subsequent Amgen-Teva Settlement Agreement**

After the Amgen-Sun settlement and dismissal of Sun's claims, other defendants in the consolidated infringement action proceeded to trial. On August 24, 2018, I entered a judgment of non-infringement in favor of Piramal Healthcare UK Ltd., Amneal Pharmaceuticals LLC, and Watson.<sup>4</sup> (J. Order, ECF No. 386.) Despite this judgment, Watson could not yet enter the market because its ANDA was still pending approval of the Food and Drug Administration. (Amgen's Br., ECF No. 455, at 7.)

On December 27, 2018, the FDA approved Watson's Cinacalcet ANDA. ([Id.](#)) On December 28, 2018, Watson, through its corporate parent, Teva, launched a generic Cinacalcet product, infiltrating the market with approximately six-weeks-worth of stock through its distribution network. ([Id.](#)). Shortly thereafter, on January 2, 2019, Amgen and Teva reached a settlement agreement whereby Teva acknowledged that its generic product infringed the '405 patent and agreed that it would immediately cease sales of this product. ([Id.](#)) Importantly, downstream distributors who had received Teva's generic product were not involved in these

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<sup>3</sup> On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

<sup>4</sup> On September 20, 2018, Amgen filed a timely appeal of the judgments of non-infringement. (Notice of Appeal, ECF No. 397.)

negotiations, nor were they parties to the Agreement. (See Agreement, ECF No. 437). Also, on January 2, 2019, in order to comply with its notification duties outlined in section 5.3 of the Agreement, Amgen notified Sun of Teva's launch and of their subsequent settlement. (Agreement, ECF No. 437-1, § 5.3; Letter, ECF No. 455-1, Ex. D.)

### **C. Relevant Portions of the Litigation Settlement Agreement**

Sun premises its position that it is entitled to a license on Section 5 of the Agreement, which is titled "LICENSE." I will briefly summarize the relevant terms of Section 5.

Section 5.1 states that from "the Entry Date through the expiration of the last to expire claim of the Licensed Patents," Sun and its Affiliates will be given a right and license to "make, have made, use, sell, offer to sell, import and distribute the Defendant's Product in or for the United States." (Agreement, ECF No. 437-1, § 5.1.)

Section 5.2 defines the "Entry Date" as the earlier of certain events which are set forth in sections 5.2(a) and (b). Section 5.2(a) is not pertinent to resolution of this motion. Section 5.2(b) states that the "Entry Date" could be the earlier of "the Launch of a Generic Cinacalcet Product by a Third Party, Amgen, or an Amgen Affiliate, except as provided under Section 5.5." (Id. at § 5.2(b) (emphasis added). Section 1 of the Agreement further defines the underlined terms.

According to Section 1, the term "Launch" means the "first sale in the United States, with regard to a Generic Cinacalcet Product." (Id. at § 1.9.) The term "Generic Cinacalcet Product" means "an oral drug product containing Cinacalcet HCL that is sold, offered for sale or distributed in the United States as an Authorized Generic or under an FDA finally approved ANDA that refers to and is AB rated with the Amgen Product as the reference-listed drug." (Id. at § 1.4.) Finally, "Third Party" is defined as "any entity or person that is not a Party or an Affiliate of a Party." (Id. at § 1.6.) Substituting these definitions into Section 5.2(b), as I have done in bold below, provides

a clearer understanding of the meaning of this Section 5.2(b):

For the purposes of this Settlement Agreement, the “Entry Date” shall mean the earlier of:

**the first sale in the United States, with regard to a Generic Cinacalcet Product (an oral drug product containing Cinacalcet HCL that is sold, offered for sale, or distributed in the United States as an authorized generic or under an FDA finally approved ANDA that refers to and is AB rated with the Amgen Products as the referenced listed drug) by any entity or person that is not a Party or an Affiliate of a Party, Amgen or an Amgen Affiliate, except as provided by section 5.5.**

Importantly, the last portion of Section 5.2(b) references Section 5.5. Section 5.5 outlines Amgen’s obligations if a Third Party engages in an “At-Risk Launch.” It states:

If a Third Party Launches a Generic Cinacalcet Product without authorization ... from Amgen and there has not been a Final Court Decision of non-infringement and/or invalidity of the Licensed Patents with respect to the Generic Cinacalcet Product that in fact was the subject of the Third Party Launch (an “At Risk Launch”) then:

- (a) If within ten (10) Business Days from Defendants having provided Amgen formal written notice of an At Risk Launch, Amgen does not ... (ii) enter into an agreement with each such Third Party selling such Generic Cinacalcet Product requiring each such Third Party to cease and desist from selling such Generic Cinacalcet Product form the market within 30 days of such agreement, then Amgen will not seek a temporary restraining order or preliminary injunction against Defendants making, having made, selling, offering to sell, importing and distributing the Defendant’s Product at risk, provided none of the Defendants’ at risk making, having made, sales, offer for sale, importation, or distribution begin before the date that is the eleventh (11th) Business Day after the At Risk Launch (subject to 5.4) and Defendants’ at risk making, having made, sales, offer for sale, importation, or distribution cease on such date as the Third Party’s Generic Cinacalcet Product is no longer offered for sale, whether by mutual agreement or otherwise. Defendants shall give Amgen notice immediately upon deciding to begin temporarily making, having made, selling, offering to sell, importing and/or distributing the Defendant’s Product under this Paragraph of the Settlement and agree that such temporary making, having made, selling, offering to sell, importing, and distributing shall end on such date as the Third Party Generic Cinacalcet Product is no longer offered for sale, whether by mutual agreement or otherwise. Defendants shall also make commercially reasonable efforts to remove the Defendants’ Product from

sale in the United states if the Third Party is also required to remove its Generic Cinacalcet Product from sale in the United States.

(*Id.* at § 5.5).<sup>5</sup> It is worth emphasizing that the first part of section 5.5 explains that an “At Risk” Launch occurs when a “Third Party” launches a Generic Cinacalcet Product without authorization.

## **II. DISCUSSION**

Amgen argues that the court does not have subject matter jurisdiction to hear this dispute. Given the notification by Amgen to Sun that Sun was not authorized to launch their Product pursuant to the Agreement, along with the Stipulation of Dismissal, Section 8.3 which states that the court shall retain jurisdiction over the Agreement, I find that there is jurisdiction to hear Sun’s motion to enforce the Agreement.

Sun urges that, based on Amgen’s deficient response to Teva’s market entry, it is entitled to a license to sell its generic Cinacalcet. (See generally Sun Br.) I conclude that Sun’s proposed interpretation of the Agreement is not correct because it would require finding that the parties intended to include substantial contractual language that is starkly absent in the Agreement. Such a result would not align with the intentions manifested in the Agreement, and thus does not trigger Sun’s license under section 5.2. The basis for these conclusions follows.

### **A. Subject Matter Jurisdiction**

#### **1. The Parties’ Positions**

In response to Sun’s motion to enforce, Amgen first argues that this court lacks subject matter jurisdiction because there is no case or controversy. (Amgen’s Br., ECF No. 455, at 9). Amgen posits that there is no real controversy and that Sun is seeking an advisory opinion from

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<sup>5</sup> There are two subparts to Section 5.5 – an (a) and (b). According to Sun, Section 5.5(b) addresses what should occur if Sun would go to market during a Third Party at Risk Launch (Sun motion, p. 6). This did not occur. And Amgen does not seem to rely on 5.5(b). Therefore, I have not set forth that subpart.

the court. Amgen presses that Sun’s motion to enforce the settlement agreement does not create jurisdiction, unless there has been a breach of contract allegation, and because no such allegation has been raised, there is no jurisdiction. (*Id.* at 9-10.)

Sun disagrees and responds that Amgen’s implicit threat of litigation created a justiciable controversy, and in any event, both the Agreement and the Stipulation of Dismissal state that the court shall retain jurisdiction to resolve any disputes under the Agreement. (Sun’s Reply Br., ECF No. 465, at 1-2.) Sun asserts that there is a case or controversy to be heard, and thus there is jurisdiction, primarily because Amgen notified Sun, after the Teva launch, that Sun could not enter the market. (*Id.* at 1-3.) Sun further explains that it is prepared to enter the market, and has made substantial investments into its generic product to reach an injunction type controversy, which would ultimately bring the same issue before the court. (Oral Ar. Tr. at 28-29, ECF No. 481, June 13, 2019.)

## **2. Analysis**

Generally, a district court has jurisdiction to enforce a settlement agreement entered into by litigants in a case pending before it. *Leonard v. Univ. of Del.*, 204 F. Supp. 784, 786 (D. Del. 2002). In discussing jurisdiction in the declaratory judgment context, the United States Supreme Court has stated that “the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotations omitted).

Courts must look to the facts of each case to differentiate between hypothetical and actual controversies. *Tabletop Media, LLC v. AMI Entm’t Network, LLC*, 2017 WL 4511351, at \*3 (D. Del. Oct. 10, 2017). Immediacy and reality are satisfied by allegations of “(1) an injury-in-fact,

i.e. a harm that is concrete and actual or imminent ... (2) that is ‘fairly traceable’ to the defendant’s conduct, and (3) redressable by a favorable decision.” Prasco LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1338 (Fed. Cir. 2008). Adverse parties must have a dispute over “legal rights, i.e., ‘an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring.’” Tabletop Media, 2017 WL 4511351, at \*3.

In the patent context, “the case or controversy requirement may be satisfied if the patentee affirmatively puts the other party in the position where the party must ‘either pursu[e] arguably illegal behavior or abandon that which he claims a right to do.’” Id.; see also, Prasco, 537 F.3d at 1339.

Here, Amgen has asserted its right to prevent Sun from entering the market. The January 2, 2019 letter to Sun from Amgen’s counsel clearly illustrates this point. In that letter, Amgen advises that it had received information about an anticipated launch by Watson (Teva), and that subsequently Teva had agreed to cease selling its generic product. Amgen then affirmatively advises Sun that it is not “authorized to launch their Product pursuant to Paragraph 5.5(a), of the Litigation Settlement Agreement.” (Letter, ECF No. 437-1, Ex D.) In response to this letter, Sun has pressed its rights to a license under the Agreement, and Amgen has vigorously opposed Sun’s position that they obtained a license to enter the market. Under these circumstances, Sun certainly has a reasonable apprehension of litigation should it choose to act upon its interpretation of the Agreement.

Amgen also argues that jurisdiction is lacking because Sun’s motion rests on anticipation of an event (e.g. launch) that may or may not occur—that is, whether Sun will sell Cinacalcet. Amgen asserts that “Sun does not allege that it intends to, and is in fact prepared to, start selling generic product immediately.” (Amgen’s Br., ECF No. 455, at 9.) But this is not the case. At

oral argument on Sun’s motion, I specifically asked Sun’s counsel when they planned to launch and they responded, “in a couple weeks.” (Oral Arg. Tr. at 28-29, ECF No. 481, June 13, 2019.) This representation further creates a reasonable apprehension of litigation necessary to defeat Amgen’s lack of jurisdiction arguments.

The language of the Agreement provides another reason to find that jurisdiction exists. Section 8.3 states, “Defendants and Amgen agree that the United States District Court for the District of Delaware retains jurisdiction over this Settlement Agreement and that the Parties agree that they are subject to personal jurisdiction in District of Delaware and/or venue is proper in the District of Delaware with regard to all disputes concerning the Settlement Agreement.” (Agreement, ECF No. 437-1, § 8.3.) The parties’ Stipulation of Dismissal also expressly states that “[t]he Court retains jurisdiction over Plaintiff and Defendants for purposes of enforcing the terms of the Settlement Agreement and this Stipulation of Dismissal and Order.” (Stip. of Dismissal, ECF No. 253.)

For all of the above reasons, I conclude that I have jurisdiction to resolve the parties dispute over the Agreement.

## **B. The Agreement Does Not Grant Sun a License**

### **1. The Parties’ Positions**

Sun urges that, based on Amgen’s deficient response to Teva’s market entry, it is entitled to a license to sell its generic Cinacalcet. Sun’s argument rests primarily on its claim that despite Teva’s launch and downstream sales, Amgen did not contract with each downstream distributor to effectuate a cease and desist regarding the selling of the Teva product. Per Sun’s reading of the Agreement, such authorized downstream sales trigger application of section 5.2 of the Agreement, thus granting Sun a license to enter the market. (See generally, Sun’s motion to enforce and reply

brief, ECF No. 465).

Amgen's response focuses on several sections of the Agreement. First, Amgen notes that a "Launch" under section 5.2(b) is defined under section 1.9 as "the first sale in the United States, with regard to a Generic Cinacalcet Product." (Amgen's Br., ECF No. 478, at 13.) In conjunction with that language, Amgen also references section 1.4 where Generic Cinacalcet Product is defined as "an oral drug product containing Cinacalcet HCL that is sold, offered for sale, or distributed in the United States as an Authorized Generic or under an FDA finally approved ANDA that refers to and is AB rated with the Amgen Product as the reference-listed drug." (Oral Ar. Tr. at 34-35, ECF No. 481, June 13, 2019.) Relying on these two definitions, Amgen argues that the downstream sales by distributors that Sun relies upon were not a "Launch" that would trigger a license under section 5.2(b), because downstream sales can never be "the first sale in the United States" of the particular generic in question. (Id.)

Amgen also emphasizes that an at-risk launch, like Teva's launch, does not trigger a license under section 5.2, unless the exceptions of section 5.5 apply. (Id.) Focusing on these exceptions, Amgen stresses that it entered into a settlement agreement with Teva within ten business days of Teva's at-risk launch, fulfilling its duties under section 5.5(a)(ii), thus preventing Sun from obtaining a license under section 5.1.

## **2. Analysis**

While the Agreement is multi-layered, its interpretation essentially depends on whether Amgen was obligated to effectuate a cease and desist not only with Teva, after Teva briefly entered the market, but also with distributors who had received Teva's product.

The United States Court of Appeals for the Third Circuit has stated that "[a] settlement agreement is a contract and is interpreted according to local law." Wilcher v. City of Wilmington,

139 F.3d 366, 372 (3d Cir. 1998); Shell's Disposal & Recycling, Inc. v. Lancaster, 504 F. App'x 194, 200 (3d Cir. 2012). “Basic contract principles apply to settlement agreements.” Williams v. Metzler, 132 F.3d 937, 946 (3d Cir. 1997).

The Agreement provides that it shall be construed and governed by Delaware law. (Agreement, ECF No. 437-1, § 8.3.) Under Delaware law, a contract is ambiguous when “the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings.” Rhone-Poulenc Basic Chem. Co. v. Am. Motorists Ins. Co., 616 A.2d 1192, 1196 (Del. 1992); see also Eagle Indus. v. DeVilbiss Health Care, 702 A.2d 1228, 1231 (Del. 1997) (stating that ambiguity arises when provisions are reasonably susceptible to at least two possible meanings). The appropriate test for ambiguity in a contract is “not what the parties to the contract intended it to mean, but what a reasonable person in the position of the parties would have thought it meant.” Rhone-Poulenc, 616 A.2d at 1196. To preserve the expectations that formed the basis for the contractual relationship, the court must consider the contract as a whole and give effect to each provision of the agreement. GMG Capital Inc. v. Athenian Venture, 36 A.3d 766, 779 (Del. 2012). While the intention of the parties will be given priority, a single provision will not be construed in a way that controls the entire agreement and runs counter to the agreement’s overall scheme or creates an absurd result. See E.I. du Pont de Nemours v. Shell Oil Co., 498 A.2d 1108, 1113 (Del. 1985); FriendFinder Network Inc. v. Penthouse Glob. Media, Inc., 2017 WL 2303982, at \*13 (Del. Ch. May 26, 2017).

Sun’s position that it is entitled to a license is based on several sections of the Agreement. Sun first notes that, under Section 5.1 and 5.2(b), an “Entry Date” of “Generic Cinacalcet by a Third Party” occurred on December 28, 2018, when Teva launched its generic Cinacalcet product. Sun then references the Agreement’s definition of “Third Party” which states that a “Third Party”

is “any entity or person that is not a Party or an Affiliate of a Party.” (Agreement, ECF No. 437-1, § 1.6.) Sun argues that the broad definition of “Third Party” includes not only Teva, but also third-party distributors who received and distributed the generic Cinacalcet for a short period of time. And because Amgen did not enter into a cease and desist agreement with Third Party distributors, Sun urges that under the Agreement, Amgen has granted Sun a license to distribute its generic Cinacalcet. In short, according to Sun, not only was Amgen required to police Teva’s initial launch sales, but additionally, Amgen was required to “adequately police the market of all third-party entities selling the Generic Cinacalcet product”. (Sun’s Br., ECF No. 437, at 5-6.)

Sun is correct that the definition of “Third Party” under § 1.6 is broad and, when read in a vacuum, could arguably encompass third-party distributors. But Sun ignores the fact that Section 5.2(b), where the term “Third Party” appears, also plainly states that “the Launch of a Generic Cinacalcet Product” is subject to the provisions of Section 5.5 (emphasis added). Thus, the wording of Section 5.5 must be analyzed.

The pertinent language of Section 5.5 is set forth on page 5 of this Opinion. The language from this Section contains various conditions and provisos, takes many detours, and is difficult to untangle.

Section 5.5 has 3 subparts: a preamble, subpart (a), and subpart (b). Starting with the preamble, the parties agree that the first part of the preamble, requiring that a third party must launch without authorization, occurred when Teva launched on December 28, 2018. (Oral Arg. Tr. at 20, 35, ECF No. 481, June 13, 2019.) As for the second preamble requirement, there is also agreement that this requirement has been met because there has not been a final court decision of non-infringement regarding Teva’s generic. (Oral Arg. Tr. at 36, ECF No. 481, June 13, 2019.) Indeed, the infringement case between Amgen and Teva is still pending in the Federal Circuit.

The next section, section 5.5(a), states that if within 10 days of notice of at risk launch, Amgen does not: (i) file a temporary restraining order or preliminary injunction “prohibiting any further sale of such Generic Cinacalcet Product, or (ii) enter into an agreement with each such Third Party selling such Generic Cinacalcet Product requiring each such Third Party to cease and desist from selling such Generic Cinacalcet Product from the market within 30 days of such agreement, then Amgen will not seek a temporary restraining order or preliminary injunction” against Sun if Sun were to distribute its generic at risk. (Agreement, ECF No. 437-1, § 5.5.)

Untangling this language and reading it in conjunction with relevant definitions, I conclude that Section 5.5(a)(i)(ii) means that if Amgen has entered into an effective cease and desist with Teva, then Amgen has complied with this section and may seek a temporary restraining order or preliminary injunction if Sun enters the market at risk. Put another way, a license to Sun has not been granted.

Amgen stresses it complied with Section 5.5(a)(ii) as it did in fact enter into a cease and desist agreement with Teva five days after Teva entered the market. Sun reads this language differently, urging that it obligates Amgen to effectuate “any further sale of such Generic Cinacalcet Product” by both Teva and all Third-Party distributors. In short, relying on language that simply does not exist, Sun insists that Amgen must have “policed the market,” – that is, policed both Teva and Third-Party distributors. I disagree with Sun’s interpretation for several reasons.

First and foremost, Amgen’s cease and desist obligations under the Agreement refers to Third Parties who engaged in at risk launch. (See Agreement, ECF No. 437-1, § 5.5) (emphasis added.) It is undisputed that distributors and resalers did not engage in at-risk launch – only Teva did. Thus, reading the agreement as a whole, I conclude that a “Third Party” does not include distributors.

As noted several times, section 5.5 is only triggered when a “Third Party Launches a Generic Cinacalcet Product without authorization ....” Once notified of that launch, Amgen did as it was obligated to do – “(ii) enter into an agreement with each such Third Party selling such Generic Cinacalcet Product requiring each such Third Party to cease and desist from selling ....” The Agreement is absolutely silent that this obligation also includes distributor resales and downstream purchasers. In fact, the Agreement plainly speaks to, and is only triggered by, an at-risk launch or a launch which is defined as the “first sale” of a generic. (Agreement, ECF No. 437-1, § 1.9.) It is undisputed that the first sale of generic Cinacalcet was by Teva and not third-party distributors.

Second, there simply is no language in the Agreement to support Sun’s contention that Amgen agreed to remove all generic products from the market, or that Amgen had a duty to police the entire market after such a launch. Sun’s interpretation of section 5.5 is only possible if I were to find that the terms “Launch” and “selling” are identical within the Agreement. Such a reading would however render the section 1.9 definition of “Launch” meaningless. Construing the term “Launch,” as Sun proposes, to also include selling by Third Party distributors would place burdensome duties on Amgen that were not expressly agreed upon in the drafting of the Agreement.

Indeed, the term “such,” which precedes “Third Party” in Section 5.5(a) serves as limiting language and supports my conclusion. Read as a whole, the phrase “each such Third Party” language used in Section 5.5(a)(ii) relates back to, and references the party identified in the first sentence of section 5.5: “If a Third Party Launches a Generic Cinacalcet Product without authorization.” (Id. at § 5.5.) Reading section 5.5 as a whole, “each such Third Party” can only refer to Teva because only the generic manufacturer has the ability to be the first to sell the specific

generic Cinacalcet product in the United States. And Teva was the only third party to have “Launched” a generic Cinacalcet. (*Id.*) By reaching an agreement with Teva to cease and desist its sales of its generic product, Amgen successfully complied with the terms of section 5.5, again preventing Sun from obtaining a license under section 5.2.

### **III. CONCLUSION**

For all the reasons set forth above, the Litigation Settlement Agreement will be enforced in accordance with the plain meaning of the terms as used and defined in the Agreement. Under this construction, Sun is not granted a license to market its Generic Cinacalcet Product at this time.<sup>6</sup>

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<sup>6</sup> Sun also requested limited discovery concerning agreements between Amgen and Teva made before the December 28, 2018 Teva Launch. This motion is DENIED because insufficient facts were plead to show a likelihood that such prior agreements were made. An appropriate order follows from this opinion.